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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,673	08/27/2001	David H. Gorski	22311/04015	5565

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EXAMINER
HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
1652	14

DATE MAILED: 08/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/940,673	GORSKI ET AL.	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,13,18,23,28 and 33-47* is/are pending in the application.

4a) Of the above claim(s) *1,5,13,18,23,28,33-40,43 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41,42,44,46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1, 5, 13, 18, 23, 28, 33-47 are at issue and are present for examination.

Election/Restrictions

Applicant's election without traverse of Group V, Claims 41, 42, 44, 46 and 47 in Paper No. 13 is acknowledged.

Claims 1, 5, 13, 18, 23, 28, 33-40 and 45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

As previously stated to applicants claims 41 and 47 will be examined to the extent that they read on the elected invention, which is SEQ ID NO: 4.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Applicants filing of information disclosures, Paper No. 4, filed 12/3/2001, is acknowledged. Those references considered have been initialed.

Drawings

The drawings filed on 2/9/2000 have been approved by the draftsperson, however the drawings (i.e. Figure 1) are objected to for the reasons discussed below with respect to the codon "TGG" and the encoded amino acid. Note, applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Specification

The disclosure is objected to because of the following informalities:

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s):

Figures 1 and 3 contain sequence disclosures. Sequence identifiers for these sequences must be used either in the drawing or in the Brief Description of the Drawing. See M.P.E.P. Section **2422.02** :

> **2422.02** The Requirement for Exclusive Conformance; Sequences Presented in Drawing Figures,
> ... It should be noted, though, that when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") **must be used, either in the drawing or in the Brief Description of the Drawings**.

The following portions of the specification list nucleic acid sequences which do not have associated with them a sequence identifier: Page 8, line 10-11, page 16, lines 5-15, page 22, lines 26-27 and page 31, line 15-19.

Applicants state that figure 1 is the nucleotide sequence of rat Gax gene with the predicted amino acid sequence and applicants also state that the rat Gax protein corresponds to SEQ ID NO: 2, however a comparison of the amino acid sequence of Figure 1 and that of SEQ ID NO: 2 reveals that these are in fact not the same sequences. For example both amino acid sequences are 303 amino acids in length, however the amino acid at position 189 of Figure 1 is a lysine, while the amino acid at position 189 of SEQ ID NO: 2 is an arginine. As applicants have chosen to limit all of the currently examined claims by SEQ ID NOs, it is critical that the information conveyed by the SEQ ID NOs is accurate. Applicants are directed to either correct this situation or appropriately explain.

In Figure 1, the rat sequence, applicants translate the codon "TGG" as a asparagine residue, whereas in Figure 3, and in SEQ ID NO: 1/2, which presumably corresponds to Figure 1, applicants translate the codon "TGG" as a tryptophan residue. Applicants are directed to either correct this situation or appropriately explain.

Appropriate correction is required.

Claim Objections

Claims 41, 42, 44, 46 and 47 are objected to because of the following informalities:

In claims 41, 42 46 and 47 applicants recite "SEQ. ID. NO." whereas in claim 44 applicants recite "SEQ ID NO." The sequence listing recites "SEQ ID NO:". It is suggested that applicants maintain consistency throughout the application.

Claims 41, and 47 are drawn to nonelected subject matter (i.e. SEQ ID NO: 2). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41, 42, 44, 46 and 47 are, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 41, 42, 44, 46 and 47 are indefinite in the recitation "Gax protein" as the specification fails to teach which identifying characteristics distinguish a "Gax protein" from other proteins. While the specification teaches some characteristics of the disclosed proteins (for example, the ability to inhibit vascular smooth muscle cell proliferation, and a molecular weight of between 30 and 36 kDA, etc.) the specification fails to define which of these characteristics are necessary for inclusion of a protein which is distinct in sequence from SEQ ID NO: 2 or SEQ ID NO: 4 to be considered to be within this class. Only after testing every protein with this common structural feature and molecular weight can one of ordinary skill in the art determine if a protein is encompassed by the claims. Therefore, the metes and bounds of the claims cannot be

ascertained because it is not known what is encompassed or excluded by the language of a "Gax protein".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41, 42 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 41 and 42 are directed to all possible mammalian or human Gax proteins having a molecular weight of 30 to 36 kDa and comprising a homeodomain which comprises the amino acid sequence of amino acids 185 through 245 of SEQ ID NO: 4. The specification, however, only provides a two representative species, one from rat and one from human encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship for the disclosed species (i.e. the inhibition of vascular smooth muscle cell proliferation). The specification also fails to describe additional representative species of these proteins by any identifying structural characteristics or properties other than the activity recited in claim 41 (i.e. the inhibition of vascular smooth muscle cell proliferation), for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full,

clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Newly added claim 46 is rejected under 35 U.S.C. 112, first paragraph because the recitation "...and an amino acid sequence comprising: (a) a first region comprising amino acid 1 through amino acid 57 and amino acid 59 through amino acid 67 of SEQ. ID. No.4; (b) a second...amino acid through amino acid 290, and amino acid 292 through amino acid 302 of SEQ. ID. NO. 4." Is not supported by the original specification and therefore considered new matter.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 41, 42 and 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a protein which inhibits vascular smooth muscle cell proliferation, having the amino acid sequence of SEQ ID NO: 4, does not reasonably provide enablement for any nucleic acid encoding any mammalian Gax protein which inhibits vascular smooth muscle cell proliferation and comprising a homeodomain which comprises the amino acid sequence of residues 185 through 245 of SEQ ID NO: 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 41, 42 and 47 are so broad as to encompass any mammalian or human Gax protein which inhibits vascular smooth muscle cell proliferation, having a molecular weight of 30 to 36 kDa and comprising a homeodomain which comprises the amino acid sequence of amino acids 185 through 245 of SEQ ID NO: 4. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to those protein having the amino acid sequence of SEQ ID NO: 2 and 4.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the

desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any mammalian Gax protein because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting protein activity; (B) the general tolerance of a Gax protein to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the ability to inhibit vascular smooth muscle cell proliferation claimed and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), it would require undue experimentation for one skilled in the art to arrive at the majority of those proteins of the claimed genus having the claimed activity of inhibiting vascular smooth muscle cell proliferation.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any protein with any number of amino acid modifications of any Gax protein. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those nucleic acids encoding proteins having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 41 and 47 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gorski et al. (Molecular and Cellular Biology (1993) 13:3722-3733, reference AL of IDS).

Gorski et al. teach the rat Gax cDNA sequence, which is identical to the claimed sequence in figure 1 and SEQ ID NO:1 and the encoded protein from rat. Gorski et al. teach the inhibition of vascular smooth muscle cells by the Gax protein (see figure 1). Gorski et al. further fused the Gax open reading frame in frame to the pQE-9 *E. coli*

expression vector and expressed it in bacteria and isolated the produced protein by SDS-polyacrylamide gel electrophoresis. Gorski et al. further state that the extracts of these Gax producing cells displayed a weak binding activity for the AT-rich Mhox-binding site in the creatine kinase enhancer. Gorski et al. thus anticipates claim 41 and 47 to an isolated mammalian Gax protein with the defined characteristics, however as applicants may argue that Gorski et al. did not actually express

Gorski et al. although authored by the inventors, also includes other non-inventors and therefore is considered "by others" and constitutes prior art. Filing of a declaration pursuant to In re Katz USPQ 14 (CCPA 1982) would be sufficient to overcome this rejection.

Claims 41 and 47 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Candia et al. (Nucleic Acids Res. 21(21): 4982, October 1993, reference AN of IDS).

Candia et al. teach the amino acid sequence of Mox-2, a mammalian Gax protein having a molecular weight of approximately 30-36 kDa and comprising a homeodomain which comprises the amino acid sequence of amino acids 185 through 245 of SEQ ID NO: 4, comprises an OPA transcribed repeat and is at least 97% identical to SEQ ID NO: 4. While Candia et al. do not disclose if this protein has the ability to inhibit smooth muscle cell proliferation, but it meets the structural limitations of the claims and would therefore be expected to have the claimed property of inhibiting smooth muscle cell

proliferation, absent clear and convincing evidence to the contrary. Thus claims 41 and 47 are anticipated by Candia et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 41, 42, 44, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Candia et al. (Development (1992) 116: 1123-1136)., reference AQ of IDS) as evidenced by Candia et al. (Nucleic Acids Res. 21(21): 4982, October 1993, reference AN of IDS).

Candia et al. teach the isolation of the nucleic acids that encode the mouse proteins Mox-1 and Mox-2 and define a novel homeobox gene family. Candia et al. describe a DNA encoding a protein with a homeobox and a molecular weight of approximately 30-36 kDa (see Figure 1A on page 1126). This protein is called Mox-1. Candia et al. do not disclose if this protein has the ability to inhibit smooth muscle cell proliferation, but it meets the structural limitations of the claims and would therefore be expected to have the claimed property of inhibiting smooth muscle cell proliferation, absent clear and convincing evidence to the contrary.

Candia et al. also describe a DNA encoding a protein called Mox-2. (See Figure 1B legend on page 1126; page 1125, column 2, paragraph following "Genomic structures" and column 1, paragraph following "Isolation of Mox-1 and Mox-2".) This is

also a protein with a homeobox and a molecular weight of approximately 30-36 kDa. Again, Candia et al. do not disclose if this protein has the ability to inhibit smooth muscle cell proliferation, but it meets the structural limitations of the claims and would therefore be expected to have the claimed property of inhibiting smooth muscle cell proliferation, absent clear and convincing evidence to the contrary.

Candia et al. do not disclose the nucleic acid sequence of the DNA molecule which encodes the Mox 2 protein, although they were in possession of the 2.2 kb clone which does indeed encode the Mox-2 protein as evidenced by a later reference of Candia et al. in which the complete amino acid sequence of Mox-2 was provided (Candia et al. Nucleic Acids Res. 21(21): 4982, 1993) which was obtained from the 2.2 kb fragment which was isolated in Candia et al. (1992), and wherein the fragment encodes a homeoprotein of 303 amino acids in length. In fact, the Mox-2 protein is exactly the same size as the claimed "Gax" protein and differs by only 2 amino acids (see Figure 1 of Candia et al. (1993)). Further, the Mox-2 homeodomain comprises the identical amino acid sequence as that of the rat and human Gax proteins, that is the homeodomain comprising amino acid 185-245 of SEQ ID. NO:4. The Candia et al. (Nucleic Acids Res. 21(21): 4982, October 1993 reference is not used as prior art but merely as evidence to show an inherent characteristic of a compound taught in the prior art (see MPEP 2131.01(d)). Therefore, the 2.2 kb clone which was possessed by Candia et al., clearly was an isolated DNA which encoded Mox-2 and said encoded protein meets all of the limitations of the instant claims 41 and 47.

Candia et al. do not disclose anything about the amino acid sequences encoded by the DNAs of Candia et al. nor disclose that the DNAs encode a protein having a molecular weight of 30 to 36 kDa . Candia et al. state that complete sequence information had not been determined because "of G-C richness and compressions" (see

page 1124, column 2, paragraph 1). This is a common difficulty in DNA sequencing in molecular biology, however, the lack of DNA and/or amino acid sequence information does not mean that Candia et al. was not in possession of the DNA encoding Mox-2 in the 2.2 kb clone. The sequence information of the DNA possessed by Candia et al. is an inherent property/characteristic possessed by the Candia DNA. The M.P.E.P. § 2141.02 states:

> "In determining whether the invention as a whole would have been obvious under section 103, we must first delineate the invention as a whole. In delineating the invention as a whole, we look not only to the subject matter which is literally recited in the claim in question. . . but also those properties of the subject matter that are inherent in the subject matter and are disclosed in the specification. . . Just as we look to a chemical and its properties when we examine the obviousness of a composition of matter claim, it is this invention as a whole, and not some part of it, which must be obvious under section 103." *In re Antonie* , 559 F.2d 618, 195 USPQ 6, 8 (CCPA 1977) (emphasis in original) (citations omitted) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal. / sq. ft. The court found the invention as a whole was the ratio of 0.12 and its inherent property that the claimed devices maximized treatment capacity regardless of other variables in the devices. The prior art did not recognize that treatment capacity was a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result-effective variable.). See also *In re Papesch* , 315 F.2d 381, 137 USPQ 42, 51 (CCPA 1963) ("From the standpoint of patent law, a compound and all its properties are inseparable.").

One of skill in the art at the time of filing would have been motivated to express the encoded protein of both Mox-1 and Mox-2 in order to further characterize these representatives of this new homeobox gene subfamily, thus making obvious claims 41 and 47. The reasonable expectation of success comes from the high degree of skill in the art of protein production once a cDNA clone has been isolated. The many

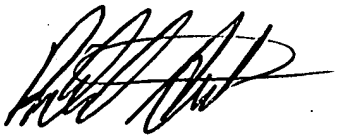
advantages of recombinant production of useful proteins are well known within the art as are recombinant methods of obtaining the necessary genes. These advantages include the ability to produce much larger quantities of the protein, being able to produce the protein in more easily handled organisms, reducing the number of steps necessary for the purification of a protein and producing the protein in a purer form by using an organism that does not include naturally occurring contaminants of the protein.

One of skill in the art at the time of filing would have further been motivated to isolate the human homologs of Mox-1 and Mox-2 and express these genes in a similar fashion as means of further characterizing the human counterparts of the Mox genes thus making obvious claims 42, 44 and 46. The reasonable expectation of success comes from the high level of knowledge in the art of identifying homologs of previously isolated genes between species and high degree of similarity between the homeobox genes in different vertebrates, as illustrated by the conservation of the homeobox domains between species.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh